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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,237	05/23/2006	Christopher Penney	GRT/4141-20	1942
23117 7590 06/27/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
BALASUBRAMANIAN, VENKATARAMAN				
ART UNIT		PAPER NUMBER		
1624				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,237

Applicant(s)

PENNEY ET AL.

Examiner/Venkataraman
Balasubramanian/**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 5 and 26 is/are allowed.
6) ☒ Claim(s) 2-4 and 6-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' response, which included addition of new claims 25-26, cancellation of claim 1 and amendment to claims 2-9 and 16-24, filed on 3/3/2008, is made of record. Claims 2-26 are now pending. In view of applicants' response all rejections made in the previous office action have been deemed as obviated. However, the following new grounds of rejection are applied to currently pending genus claims.

Claim Rejections - 35 USC § 112

Claims 2-4 and 6-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of B= 0 (zero) in claim 25 renders claim 25 and its dependent claims indefinite as it is not clear what is intended. Note B is not an index.
2. In claim 25, A and B choice a semicolon is needed to indicate the end of the group choice. As recited it is vague and unclear.
3. Recitation of "N-acetylanilino and anilino" in claim 25 renders claim 25 and its dependent claims indefinite as it is not clear whether attachment of these groups is through nitrogen or aromatic ring. Note there is no support for N-N bonded compounds. Hence, as recited these claims are vague and unclear as to the scope.
4. Claim 7 is an improper dependent claim as it fails to further limit claim 25 on which it is dependent. Note claim 7 includes a benzyl group bearing amino group (n=1), which is outside the scope of claim 25.

5. Recitation of "at least one" compound according to claim 25 renders claim 9 and its dependent claims 10-15, 17 and 18, indefinite as it is not clear what other active ingredient is included in these claims. Note at least one of compound of claim 25 means it can include besides compound of claim 25, it can include any other undefined active ingredients. Replacement of " at least one" by " one or more" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for non covalent binding of compound of formula shown in claim 25 to antibodies does not reasonably provide enablement for covalent binding of compound of formula shown in claim 25 to antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following apply:

In evaluating the enablement question, following factors are considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1. The nature of the invention and the state of the prior art:

The invention of claim 6 is drawn to a covalent binding of compound of formula shown in claim 25. While example 54 in page 59 show binding of the said compounds to antibodies by Elisa, which is competitive binding assay and the binding is therefore non-covalent binding. Specification has no showing that these genus of compounds indeed bind covalently to antibodies. Furthermore, the compounds shown in claim 25 have no discernable reactive functionality and hence it is not possible to know why such compounds would bind to antibodies covalently.

2. The predictability or lack thereof in the art: Hence, the covalent binding claimed as applied to the above-mentioned compounds claimed by the applicant is not an art-recognized process and hence there should be adequate enabling disclosure in the specification with working example(s).

3. The amount of direction or guidance present: Examples illustrated in the experimental section or written description offer no guidance or teachings as to how perform the covalent binding when reactive substituents are present in the said compounds.

4. The presence or absence of working examples: Although example 54 the binding assay, it is limited non-covalent binding of compounds of claim 25. There are no representative examples showing the viability of the covalent binding for plurality of non-reactive substituents embraced in the instant claims.

5. The breadth of the claims: Specification has no support, as noted above, for all compounds generically embraced in the claim language would lead to desired covalent

binding of compound of formula shown in claim 25 without any reactive groups and there is also no valid chemical reasoning for one trained in the art to expect that all these functional groups would contribute to covalent bond formation for covalent binding.

6. The quantity of experimentation needed: The quantity of experimentation needed would be an undue burden on skilled art in the chemical art since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Even with the undue burden of experimentation, there is no guarantee that one would get the product of desired covalent binding of compound of formula embraced in the instant claims.

Also, note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.". Clearly that is the case here.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of antibody-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards covalent binding of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was 'filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Allowable Subject Matter

Claims 5 and 26 are allowed, barring finding of any prior art in a subsequent search.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624